U.S. Consumer Product Safety Commission

MEETING LOG

PRODUCT: Nanotechnology

SUBJECT: ISO/TC 229 Nanotechnologies Working Group Virtual Meetings to Discuss Current Projects and Potential New Work Item Proposals (NWIPs)

LOCATION: Teleconference

DATE: November 14-18, 2022

ENTRY DATE: November 23, 2022

LOG ENTRY SOURCE: Joanna Matheson (HSTR)

COMMISSION ATTENDEES: Treye Thomas (EXHR), Isaac Mireku (LS), Joanna Matheson (HSTR)

NON-COMMISSION ATTENDEES: Contact ANSI for a complete list.

MEETING SUMMARY:

ISO Technical Committee 229 (ISO TC/229) focuses on standardization in the field of nanotechnologies, understanding and control of matter and processes at the nanoscale where the onset of size-dependent phenomena usually enables novel applications, as well as use of nanoscale materials to create improved materials, devices, and systems that exploit these new properties. Specific working groups address the development of standards and guides for terminology and nomenclature; metrology and instrumentation; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices.

On Monday November 14, 2022, the general meeting of Working Group 3 (WG3, Health Safety and the Environment) was held during which project leaders provided brief verbal updates on their respective work and their goals for the project meetings that would occur on November 14th-18th. Two presentations on potential New Work Item Proposals (NWIP), *OC/EC Thermal Optical Analysis for the Lung Burden Measurement of Carbon-Based Nanomaterials,* and *Characterization of Reassembled Metal Oxide Nanomaterials in Organs*, were given. ICP-MS is a common analytical method for determining nanomaterial lung burden, however, it cannot detect elements such as carbon and nitrogen and therefore not carbon-based nanomaterials. Other current analytical methods only provide relative quantitative values for lung burden. This proposal using OC/EC thermal optical analysis is a modified version of NIOSH method 5040 and is purported to distinguish between organic and inorganic carbon, have a low detection limit, preserve the form of the nanomaterial in the lung tissue and have a high recovery rate after tissue digestion. There was active discussion from the working group experts on the second proposed project on whether the proposed method differentiates between reassembled or biotransformed nanomaterials, on the degree of reassembly (and how that will be determined), on the applicability to all tissues as opposed to just the lung, and the determination of location within a tissue, cell or organelle of reassembly. Working group experts volunteered to help with addressing some of these issues.

From Tuesday November 15, 2022, through Friday, November 18, 2022, CPSC staff participated primarily in WG3 meetings, and participated in other working group meetings when they did not overlap with the WG3 sessions. Revisions continue for two technical standards (TS) relating to occupational risk management, TS 12901-1 *Occupational risk management applied to engineered nanomaterials Part 1: Principles and approaches* and TS 12901-2 *Occupational risk management applied to engineered nanomaterials Part 2: Control banding approach*. An update was provided on TS 7833 *Extraction method of poorly soluble nanomaterials from lung tissue by the proteinase K digestion*. Working group experts felt this was a well-developed document, but the scope needed to be revised to state that the method is applicable only for certain nanoparticles, and a warning added to the text to indicate that size and size distribution changes could occur during sample preparation. With these changes, it was proposed that after a two-week review, the method should be submitted for ballot. During the WG3 strategy meeting, a presentation was given on the European Union INKplant project and the development of relevant standards. This project develops different biomaterials for multi-material inkjet and 3D printing of next generation implants. Additional project ideas for WG3 include standards addressing long-term health effects.

WG3 held a joint meeting with WG5 (Products and Applications) on November 15, 2022, to discuss TR 23652 *Performance evaluation of radiolabeling methods for nanomaterials* and PWI 23653 *Experimental considerations when evaluating nanoparticle performance of cellular uptake*. Five types of radiolabeling methods are covered in TR 23652 along with their advantages and disadvantages. The expert group recommended adjustment to a definition and adding text for general concerns regarding handling radionucleotides. With these revisions, the working group recommended submitting the document to ISO/TC 229 for DTR ballot by the end of November 2022. For PWI 23653 the mechanism of nanoparticle cellular uptake was added to the introduction as well as an explanation of the mechanism with the measurement method of nanoparticle cellular uptake. Slight changes were made to the title to focus the title. Some working group members expressed concern that the methods did not distinguish whether the nanoparticles were in the cell versus on the cell surface. The working draft will be revised, circulated for comment and will be discussed at the next meeting in May 2023.

Experts met to discuss ISO/TS 11353 *Test method for detection of nano-object release from respiratory masks media under different working conditions*. More than 100 comments were sent by the expert group; an additional meeting will be scheduled to complete the comment review. Extensive discussion revolved around the range of velocity (*i.e*., a 50-fold range) currently stated in the draft standard, that it was too broad of a range and whether the standard should have fixed velocity (so that the same force is applied to each mask) or fixed flow rate. The working group suggested that until there is data supporting a fixed value, three face velocities (low, medium, higher) should be indicated. In addition, more information (*i.e*., what filter is used for collection, what equipment is used to collect the released particles) is needed in the sampling portion of the draft standard. There is a similar project in Working Group 5 (WG5), *Evaluation of the Performance of the Respiratory Mask Containing Nano-objects*, whose session CPSC staff could not attend. WG5 evaluated the new proposal and requested that a draft document be submitted by the end of December 2022, to allow for review and comment before a meeting with WG 5 experts at the end of January 2023. Staff are particularly interested in these projects and will continue to monitor their development.

Work continues on PWI 7666 *Assessment of chronic inhalation toxicity using intermittent exposure protocol based on lung burden of nanomaterials as a measure of internal exposure.* This document specifies a protocol for rodent 2-year inhalation carcinogenesis studies by shifting from aerosol concentration in an exposure chamber to “lung burden” as a measure of internal exposure. This protocol is based on the principle that the lung burden is strongly related to the lung toxicity profile and is therefore applicable to the evaluation of insoluble particles that are not readily biodegradable and cleared by the lungs. Working group members stated that more work is needed on the lung

clearance and lung overload sections. PWI 4962 *In vitro testing of the phototoxicity of nanoparticles*, which has NIST as a coleader, was also discussed. During this session minor changes were made to the title and scope, to terminology and to the Annexes; in addition, it was suggested that a note be inserted to indicate that there is no standard dispersion procedure. Once additional text is received from the expert group members, the document will be revised, distributed for review in December and submitted for ballot.

WG3 met on November 17 to discuss the CPSC proposed method PWI 5265 *Method for characterizing and quantifying nanomaterials released from wood products* which had been revised to reflect a TS format from its original TR format. During this session changes were made to the title and scope, narrowing the scope to specific nanomaterials. Text will be moved to the introduction and background sessions as well as to Annexes. Additional text will be added on dimensions of equipment used for the wipe method as well as on the filters used and their pre-treatment. The working group congener reminded the experts that the level of discussion occurring during this session is for a new work item (NWI) and not a preliminary work item (PWI). With these revisions, the proposed project will be balloted in two weeks to be a NWI.

Staff will continue to monitor TS10818 *Textiles Containing Nanomaterials and Nanostructures - Superhydrophobic Characteristics and Durability Assessment*. The working group met on November 17, but the quality of the call for virtual attendees was poor. The working experts recommended a revision of the DTS draft and submission of the relevant documents to ISO/TC 229 for the publication stage by the end of November 2022. PWI 12948 *Nanocomposite materials for insulating: Specification of characteristics and measurement method* did not meet. Staff are interested in this project with the potential for release of nanomaterials from nano-enabled insulation and will monitor the development of the project.

The next international meetings of ISO TC/229 will be held face-to-face in Japan in May 2023 and Germany in November 2023.